

25 November 2015

Dear Sir / Madam

Our reference: FSCA 2709

IMPORTANT : URGENT FIELD SAFETY NOTICE
ETEST® PIP/TAZO/CON-4 PTC 256

Our records indicate that your laboratory has received one or more of the following products. This letter is intended for all customers using **ETEST** kits that include the antibiotic **Piperacillin/Tazobactam** (product reference and lot numbers detailed below).

Table 1

Product Ref. Number	Description	Lot Number	Expiry date
412434	ETESTt PIP/TAZO/CON-4 PTC 256 - pack of 30 tests WW	1004331500	28-Sep-2018
		1004271120	02-Sep-2018
		1004178060	22-Jul-2018
		1003977300	29-Apr-2018
		1003697470	08-Jan-2018
		1003415090	09-Sep-2017
		1003276060	10-Jul-2017
		1003069230	07-Apr-2017
		1002488490	18-Jul-2016
		1001936360	20-Dec-2015
521418	ETEST PIP/TAZO/CON-4 PTC 256- Foam of 100 tests WW	1004398470	21-Oct-2018
		1004276460	03-Sep-2018
		1004180840	22-Jul-2018
		1003980200	29-Apr-2018
		1003699550	08-Jan-2018
		1003416920	09-Sep-2017
		1003105180	23-Apr-2017
		1002995820	19-Mar-2017
		1002482640	16-Jul-2016
		1002375410	04-Jun-2016
		1002276210	23-Apr-2016
		1002092270	20-Dec-2015



Description of the issue

Based on a low MIC report from the field, bioMérieux initiated a complaint investigation (PR 929981) to confirm product performance and determine the root cause. As a result of the investigation, the following was identified:

- Isolates (*Enterobacteriaceae* strains) were tested with agar dilution and broth micro dilution reference methods:
 - Using EUCAST breakpoints (MIC \leq 8: Susceptible; MIC $>$ 16: Resistant), **ETEST PIP/TAZO** showed a higher frequency of erroneous results – **False Susceptible** - when compared to the referenced method (Broth-Micro Dilution).
 - Performance using CLSI breakpoints (compared to the Broth Micro Dilution referenced method) was similar to EUCAST.

In conclusion, the data analysis demonstrates that the performance of **ETEST PIP/TAZO** has shifted when compared to the published performance characteristics.

A **CAPA (PR 935879)** was initiated to define the root cause and determine the long-term action plan to resolve the non-conformity.

Impact:

The risk to patients, as a result of the **ETEST PIP/TAZO/CON-4** PTC 256 performance shift, is the potential for reporting erroneous results for Piperacillin/Tazobactam; specifically **False Susceptible** results. This risk may lead to medical intervention for the patient because the erroneous result could negatively influence the selection of antibiotic therapy.

Required actions:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Discontinue using and discard any remaining inventory of **ETEST PIP/TAZO/CON-4** PTC 256 lots referenced in table1.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- Complete and return the Acknowledgement Form (**Attachment A**) by Fax for the attention of Customer Services to fax number 0044 (0) 1256 816863 Once the completed form has been received we will provide a credit for the product destroyed

We can confirm that the Competent Authorities have been advised of this Notification.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Yours sincerely



Laura Martin
Quality & Regulatory Manager

Attachment A: Acknowledgement Form – FSCA 2709

Please return for the attention of Customer Services to fax number 0044 (0) 1256 816863

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement form

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the **ETEST PIP/TAZO/CON-4** PTC 256 product issue.

Product : ETEST PIP/TAZO/CON-4 PTC 256				
412434	ETEST PIP/TAZO/CON-4 PTC 256 -pack of 30 tests WW	1004331500	Number of kits received	
			Number of kits destroyed	
		1004271120	Number of kits received	
			Number of kits destroyed	
		1004178060	Number of kits received	
			Number of kits destroyed	
		1003977300	Number of kits received	
			Number of kits destroyed	
		1003697470	Number of kits received	
			Number of kits destroyed	
		1003415090	Number of kits received	
			Number of kits destroyed	
		1003276060	Number of kits received	
			Number of kits destroyed	
1003069230	Number of kits received			
	Number of kits destroyed			
1002488490	Number of kits received			
	Number of kits destroyed			
1001936360	Number of kits received			
	Number of kits destroyed			

Cont..



Product : ETEST PIP/TAZO/CON-4 PTC 256			
521418	ETEST PIP/TAZO/CON-4 PTC 256 - Foam of 100 tests WW	1004398470	Number of kits received
			Number of kits destroyed
		1004276460	Number of kits received
			Number of kits destroyed
		1004180840	Number of kits received
			Number of kits destroyed
		1003980200	Number of kits received
			Number of kits destroyed
		1003699550	Number of kits received
			Number of kits destroyed
		1003416920	Number of kits received
			Number of kits destroyed
		1003105180	Number of kits received
			Number of kits destroyed
		1002995820	Number of kits received
			Number of kits destroyed
		1002482640	Number of kits received
			Number of kits destroyed
		1002375410	Number of kits received
			Number of kits destroyed
1002276210	Number of kits received		
	Number of kits destroyed		
1002092270	Number of kits received		
	Number of kits destroyed		

I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

Have you received reports of illness or injury related to the identified issue?

Yes or No

DATE.....

SIGNATURE :

